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REMARKS

The office action of Dec. 24, 2002 set out a restriction requirement covering the then newly submitted claims 26-51. This restriction has been maintained over the Applicants dissent. Applicant once again asserts that the subject matter of these claims is not "independent and distinct" as necessary to support a restriction requirement under 37 C.F.R. 1.142(a). Claim are "independent" when "there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect, . . ." MPEP 803.01. Claims are "distinct" when the two or more subjects are related, but are capable of separate manufacture, use, or sales as claimed AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER (though they may each be unpatentable because of the prior art)." MPEP 803.01.

As to dependent claims 26-29, Applicant asserts that the dependent nature of the claims themselves discloses the relationship to the subject matter of the claims from which they depend and that these claims are therefore not "independent." Furthermore, Applicant asserts that the subject matter of these claims 26-29 includes the subject matter of claim 1, and that claim 1 would not be patentable over the combined subject matter of claim 1 with any of claims 26-29. For these reasons, maintaining the restriction requirement is improper.

While claim 30 is written in independent form, the subject matter of claim 30 is not independent of the subject matter of claim 1. As shown in the table below, the only difference between claims 1 and 30 is the phrase "in the absence of a peroxide." Therefore, the relationship between claim 30 and claim 1 is clearly not independent. It also follows that the claims depending from claim 30 are in the nature of further dependent claims, which are also not independent.

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Claim under consideration	Claims withdrawn from consideration
1. A method of preparing a sterilizing solution, comprising: (a) storing dry solid material comprising one or more dipercarboxylic acid; and (b) dissolving the dry solid material into water as needed to prepare an aqueous sterilizing solution having a dipercarboxylic acid concentration between about 0.1 weight percent and saturation.	30. A method of preparing a sterilizing solution, comprising: (a) storing dry solid material comprising one or more dipercarboxylic acid; and (b) dissolving the dry solid material into water as needed to prepare an aqueous sterilizing solution having a dipercarboxylic acid concentration between about 0.1 weight percent and saturation, <i>in the absence of a peroxide.</i>

Claim 41 is also written in independent form, but the claim is not independent of the subject matter of claim 1. As shown in the table below, the only difference between claims 1 and 41 is the addition of the phrase "sterilizing agents consisting essentially of." While the subject matter in the remainder of claim 41 has a clear relationship to the subject matter of claim 1, this phrase makes the subject matter narrower. It also follows that the claims depending from claim 41 are narrower still.

Claim under consideration	Claims withdrawn from consideration
1. A method of preparing a sterilizing solution, comprising: (a) storing dry solid material comprising one or more dipercarboxylic acid; and	41. A method of preparing a sterilizing solution, comprising: (a) storing dry solid material comprising <i>sterilizing agents consisting essentially of</i> one or more dipercarboxylic acids; and

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(b) dissolving the dry solid material into water as needed to prepare an aqueous sterilizing solution having a dipercarboxylic acid concentration between about 0.1 weight percent and saturation.	(b) dissolving the dry solid material into water as needed to prepare an aqueous sterilizing solution having a dipercarboxylic acid concentration between about 0.1 weight percent and saturation.
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Applicant continues to assert that the restriction is improper. Applicant requests that the restriction be withdrawn and that claims 26-51 be considered.

Claims 1 – 11 and 17 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner has discussed the meaning of the term “comprising,” but does not appear to have made a rejection with regard to this phrase. Applicant agrees that the term “comprising” indicates an open group.

The Examiner has found the term “substantially free” in claim 6 to be indefinite, citing the Merriam Webster Collegiate Dictionary for the assertion that “substantially” means “ample to satisfy and nourish.” However, Applicant asserts that the Examiner is applying an inappropriate definition of the term. The Federal Circuit has declared that “[o]rdinarily, therefore, ‘substantially’ means ‘considerable in . . . extent,’ . . . or ‘largely but not wholly that which is specified.’” *York Prods., Inc. v. Central Tractor Farm & Family Ctr.*, 99 F.3d 1568, 40 USPQ2d 1619 (Fed. Cir. 1996)((quoting The American Heritage Dictionary of the English Language 1213 (2d College ed. 1982); Webster’s Ninth New Collegiate Dictionary 1176 (9th ed. 1983)). The Federal Circuit has stated that “[c]laims need only ‘reasonably apprise those skilled in the art’ as to their scope to satisfy the definiteness

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requirement. . . . In addition, the use of modifiers in the claim, like 'generally' and 'substantial,' does not by itself render the claims indefinite." *Energy Absorption Sys., Inc. v. Roadway Safety Servs., Inc.*, Civ. App. 96-1264 (Fed. Cir. July 3, 1997)(unpublished). Applicant has used the term "substantially" in a manner consistent with its widespread use in U.S. patents. Applicant requests withdrawal of this rejection. If the Examiner persists in this rejection, Applicant requests an explanation why, in the context of the present claims, the term "substantially" does not reasonably apprise those skilled in the art as to the scope of the claims.

Claims 1 – 11 and 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US 5753770 (Breitenbach et al) and US 5674538 (Lokkesmoe et al).

Breitenbach discloses a fluidized-bed process for preparing certain complexes that may include percarboxylic acids. These complexes "can be used, for example, as a disinfectant or preservative." (Breitenbach, col. 6, lines 30-32)(*emphasis added*).

Lokkesmoe has been discussed at length by the Examiner in previous office actions and by the Applicant in previous responses. Lokkesmoe discloses a process for inhibiting microbial growth in aqueous food transport or process streams. (Lokkesmoe, title). Lokkesmoe teaches that carboxylic acids can be combined with hydrogen peroxide to form an antimicrobial agent. (Lokkesmoe, col. 4, lines 45-48).

The Examiner has asserted, along with reference to the Merriam-Webster Collegiate Dictionary & Thesaurus, that "sterilize" and "disinfectant" are synonyms because they both mean "clean" and that this then leads to the conclusion that the prior art already teaches the claimed invention. Applicant asserts that the foregoing premise and conclusion are both incorrect.

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As a first matter, the terms "sterilize" and "disinfect" are both defined in applicant's specification, as follows:

To understand the value of the invention, it is imperative to distinguish between sterilization and disinfection. Strictly, *sterilization* is the use of physical or chemical means to destroy all microbial life. *Disinfection* is a less lethal process than sterilization in which most, but not all, of the microbial life is destroyed. Therefore, sterilization represents the highest possible level of disinfection. Microbial life is a broad term that encompasses many different organisms including bacterial endospores, mycobacteria, fungi, vegetative bacteria, and viruses. Bacterial endospores are the most resistant to chemical disinfectants and therefore represent the benchmark of microbial organisms in the evaluation of chemical disinfectants. If a chemical disinfectant can reduce the level of bacterial endospores by six logarithms or more it is considered a liquid sterilant. The present invention describes stable, solid peracids that can be dissolved in water at concentrations high enough to be defined as a sterilant.

Specification, page 4, lines 11-21 (emphasis added)

Therefore, the terms "sterilize," "sterilization," "sterilizing solution," or other variants of the root word "sterile," should be interpreted as being distinct from the terms "disinfect" and variants thereof. A person having ordinary skill in the art, having read the present specification and claims, would understand that a "sterilizing solution" would not only kill vegetative bacteria, but would also kill bacterial endospores as described in the specification.

Secondly, these definitions are consistent with the well known usage of these terms in the relevant art. For example, the McGraw-Hill Dictionary of Scientific and Technical Terms, 6th ed., defines a *disinfectant* as "[a] chemical agent that destroys microorganisms but not bacterial spores" and defines *sterilization* as "[a]n act or process of destroying all forms of microbial life . . ." As a further example, the U.S. Food and Drug Administration's Center for Devices and Radiological Health has published a document, issued January 3, 2000, entitled Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants. This FDA document defines *disinfection* as being "a less lethal process than sterilization, since it destroys

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most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores” and states that “[d]isinfection processes do not ensure the margin of safety associated with sterilization processes.” (Currently available at www.fda.gov/cdrh/ode/397.html). Similarly, the same FDA source defines *sterilization* as a “[v]alidated process used to render a product free of all forms of viable microorganisms.” *Id.* By contrast, this FDA source also defines *cleaning* as “[t]he removal, usually with detergent and water, of adherent visible soil, blood, protein substances, and other debris from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.” *Id.*

“When not defined by applicant in the specification, the words of a claim must be given their plain meaning. In other words, then must be read as they would be interpreted by those of ordinary skill in the art.” MPEP 2111.01. Those of ordinary skill in the art of sterilization would interpret the words “sterilizing solution,” as in present claim 1, to have a definition consistent with the specification, the McGraw-Hill Dictionary, or the FDA.

Furthermore, while the Examiner has not set out the actual definitions of the terms “sterilize” and “disinfectant” nor provided a complete enough citation to allow Applicant to review the Merriam-Webster Collegiate Dictionary & Thesaurus that the Examiner has consulted, Applicant has found that the Merriam-Webster Collegiate Dictionary, 9th ed. (1989) defines these terms in a manner consistent with the present specification – namely, it defines *disinfectant* as “a chemical that destroys vegetative forms of harmful microorganisms esp. on inanimate objects but that may be less effective in destroying bacterial spores” and defines *sterilize* as “to free from living microorganisms.”

Having shown the proper interpretation of the claim term “sterilizing solution,” Applicant asserts that this term should be given patentable weight. Indeed, functional limitations in the claims must be afforded patentable weight even if the functional limitations are the only limitations that are

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nonobvious over the prior art. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Reconsideration and withdrawal of the rejection is requested.

Still further, the cited reference to Breitenbach supports the proposition that it is important to understand and differentiate the definitions that describe the degree of antimicrobial efficacy. (Breitenbach, col. 3, line 66 – col. 4, line 3). Even so, Breitenbach discusses bacteriocidal agents (sanitizer or disinfectant) and bacteriostatic agents (preservative), but does not discuss sterilization or the killing of spores. Accordingly, Breitenbach does not provide any motivation to modify the teaching of the reference to form a sterilizing solution, nor provide any reasonable expectation of success in achieving a sterilization solution. Both the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure. *In re Dow Chem.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). It is improper to base a determination of obviousness on what the skilled person might try or find obvious to try. Rather, the proper test requires determining what the prior art would have led the skilled person to do. Here, the prior art would not have led the skilled person to prepare a sterilizing solution using dipercarboxylic acids.

Neither Breitenbach nor Lokkesmoe, alone or in combination, teach, show or suggest a sterilizing solution capable of killing spores. Rather, the claimed method provides surprising results in that it was not previously known to be possible to prepare a sterilizing solution, by following the steps comprising: (a) storing dry solid material comprising one or more dipercarboxylic acid; and (b) dissolving the dry solid material into water as needed to prepare an aqueous sterilizing solution having a dipercarboxylic acid concentration between about 0.1 weight percent and saturation.

The examiner has stated that the presently claimed invention differs from the reference in claiming specifically a formulation which is substantially free from hydrogen peroxide." Office Action of June 18, 2003 at page 4, lines 17-18. This is true as to dependent claim 6. However, Applicant has pointed out a more fundamental difference between the presently claimed invention

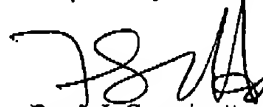
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and each of the references.

In conclusion, Applicant submits that all the remaining claims in the present application are entitled to allowance and such action is earnestly solicited.

In the event there are additional charges in connection with the filing of this Response, the Commissioner is hereby authorized to charge the Deposit Account No. 50-0714/LYNN/0120 of the firm of the below-signed attorney in the amount of any necessary fee.

Respectfully submitted,



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